DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 26, 2015

Osprey Medical, Inc.
Ms. Melanie Hess
Sr. Director, Regulatory Affairs
5600 Rowland Road, Suite 250
Minnetonka, Minnesota 55343

Re: K150485
Trade/Device Name: AVERT Contrast Modulation System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: February 23, 2015
Received: February 24, 2015

Dear Ms. Hess:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K150485

Device Name: AVERT™ Contrast Modulation System

Indications for Use:
The AVERT™ Contrast Modulation System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures with the following agents: Iodixanol 270 or 320 mgI/mL, Iohexol 300 or 350 mgI/mL and Iopamidol 300 or 370 mgI/mL.

Prescription Use __X____ AND/OR Over-The Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

510(k) Summary As required by 21CFR 807.92(c)

510(k) Number: K150485

Date Prepared: February 12, 2015

Submitter's Name/Address: Osprey Medical
5600 Rowland Road Suite 250
Minnetonka, MN 55343

Contact Person: Melanie Hess
Sr. Director, Regulatory Affairs
Tel: 952-955-8252
Fax: 952-955-8171
Mhess@ospreymed.com

Device Information:

Trade Name/Proprietary Name:	AVERT™ Contrast Modulation System
Common Name:	Injector and Syringe, Angiographic
Classification Registration:	21 CFR § 870.1650
Product Code:	DXT
FDA Center/Branch:	CDRH/Interventional Cardiology Devices Branch (ICDB)

Device Description:

The Osprey Medical AVERT™ Contrast Modulation System allows for the modulation of contrast media during manual injections in coronary or peripheral imaging procedures. The AVERT System consists of a reusable, non-sterile apparatus (contrast modulator), which applies a force to a disposable sterile modulation reservoir with a standard, off-the-shelf 4-way stopcock and extension line. The contrast modulator utilizes an internal mechanism to apply a force to the modulation reservoir; allowing for modulated diversion of manual contrast injections. The force can be easily and quickly adjusted by moving the location of the pin as identified on the outer housing of the system, thereby increasing or

decreasing the amount of force applied to the modulation reservoir. The contrast modulator is attached to a wheeled stand and is positioned near the patient, outside of the sterile field.

Indications for Use:

The AVERT™ Contrast Modulation System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures with the following agents: Iodixanol 270 or 320 mgI/mL, Iohexol 300 or 350 mgI/mL and Iopamidol 300 or 370 mgI/mL.

Predicate Device:

Trade Name/Proprietary Name:	AVERT Contrast Modulation System
Common Name:	Injector and Syringe, Angiographic
Classification Registration:	21 CFR § 870.1650
Product Code:	DXT
510(k) number(s)	K140425

Comparison to the Predicate Device:

The AVERT™ System is substantially equivalent and unchanged from the predicate AVERT™ System in that they are identical systems with the exception of the minor modification to include a new AVERT™ System model number, RMS-ISOV-300-C, with a new spring component. No modifications to performance specifications have been made. The subject device is identical to the predicate in that:

- The proposed device consists of the same material; and
- No changes have been made to the product performance specifications, sterilization process, manufacturing processes or risk assessment; and
- The intended use, indications for use and fundamental scientific technology remains unchanged.

The fundamental scientific technology, materials, sterilization process, manufacturing processes and risk assessment are unchanged from the predicate. The intended use and indications for use statement are unchanged from the predicate device. No new or different questions of safety or effectiveness are raised with the proposed modification.

Summary of Non-Clinical Testing:

Bench testing was performed or leveraged from the predicate to support the AVERT™ System and results demonstrate the AVERT™ System meets product specification and performance requirements. The following testing was successfully completed:

- Device performance testing included flow rate, peak pressure reduction, contrast diversion and flow rate adjustability. Testing was leveraged from the predicate for mechanical cycle testing, image analysis and compatibility to Osprey Medical Contrast Monitoring System. All testing passed and demonstrated product performance met all prior established acceptance criteria.
- Sterilization conditions have been validated and leveraged from the predicate in accordance with ISO 11135-1:2007, *Sterilization of health care products – Ethylene Oxide Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices* to provide a Sterility Assurance Level of 10^{-6}. All testing passed.
- Simulated use (animal) and post-market design validation was performed and leveraged from the predicate. Testing included assessment of injection pressure, contrast diversion, image analysis. Testing demonstrated no new or different question of safety or effectiveness were raised.
- Shelf-life, distribution and shipping testing was performed and leveraged from the predicate per ASTM D4169. Testing included visual inspection, cycle testing, dye leak test, seal strength test and functional testing. All testing passed and demonstrated product performance met all prior established acceptance criteria.
- Biocompatible testing was performed and leveraged from the predicate in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. Testing included cytotoxicity, sensitization, irritation (intracutaneous reactivity), systemic toxicity, hemocompatibility, genotoxicity, chemical characterization. All testing passed and meet prior established acceptance criteria.

All test results demonstrate that the materials, manufacturing processes and design of the Osprey Medical AVERT™ Contrast Modulation System meet the established performance criteria and will perform as intended.

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for angiographic injectors and syringes.

Clinical Testing:

No clinical testing was performed to support this Special 510(k) Premarket Notification.

Statement of Equivalence:

The AVERT™ System with the proposed modification is substantially equivalent in intended use, indications for use and method of operation to the predicate AVERT™ System. Based on the substantially

equivalent assessment and data collected in accordance with Osprey Medical Quality System Procedure in compliance with EN ISO 13485:2003 Medical Devices – Quality management systems – requirements for regulatory purposes and EN ISO 14971: 2012 Risk management for medical devices, the AVERT™ System has been shown to be substantially equivalent under 21 CFR Part 807 subpart E.

510(k) Summary

510(k) Summary As required by 21CFR 807.92(c)

510(k) Number: K150485

Date Prepared: February 12, 2015

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